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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/589,556

05/16/2007

Kentaro Nakamura

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EXAMINER

GERIDO, DWAN A

ART UNIT

PAPER NUMBER

1797

NOTIFICATION DATE

DELIVERY MODE

07/03/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No. 10/589,556	Applicant(s) NAKAMURA ET AL.	
	Examiner Dwan A. Gerido, Ph.D.	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 May 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 August 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :11-20-2006, 5-16-2007, 10-31-2007.

DETAILED ACTION***Double Patenting***

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-7 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7 of copending Application No. 11/060,775. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-7 recite nearly identical limitations (3 layers of an analysis element) within the same device. Claim 1 of application 11/060,775 recites the parameters for mean deviation and irregularity profile of the contact surface whereas the instant claims are silent to a mean deviation/irregularity profile. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify application 10/589,556 in view of 11/060,775 as

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determining the parameters of a result effective variable requires only routine skill in the art.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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6. Claims 1, 2, 5, and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Terashima et al., (US 4,839,278).

7. With regards to claim 1, Terashima et al., teach a multilayer analysis element comprising a functional layer, a porous liquid sample spreading layer, and a water impermeable support (abstract, column 3 lines 25-28, column 8 lines 5-18). Terashima et al., do not recite values for bending rupture strength, tensile percentage, or a tensile force. It would have been obvious to one of ordinary skill in the art at the time the invention was made to construct the test element with a bending rupture strength of 20 gram-weight, a tensile percentage of 2 percent or less, and a tensile force of 50 gram-weight as discovering an optimum value of a result effective variable requires only routine skill in the art. (see MPEP 2144 II B, and *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

8. With regards to claims 2, 5, and 6, Terashima et al., teach the analysis element comprising a porous film of organic polymers, specifically polyamide, polyurethane, polyethylene, and polypropylene (column 8 lines 5-18, 63-column 9 line 6).

9. Claims 3 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Terashima et al., (US 4,839,278) in view of Hildenbrand et al., (US 4,824,639).

10. With regards to claims 3 and 4, Terashima et al., teach a multilayer analysis element comprising a functional layer, a porous liquid sample spreading layer, and a water impermeable support (abstract, column 3 lines 25-28, column 8 lines 5-18). Terashima et al., do not teach an analysis element with an asymmetry ration of 2 or more, nor do they teach a symmetry ratio less than 2. Hildenbrand et al., teach a multilayer test strip comprising a microporous polymer layer with an asymmetric pore structure that is

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advantageous because it filters particles based on size. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Terashima et al., in view of Hildenbrand et al., to gain the advantage of utilizing an asymmetric pore structure in order to filter particulates within the sample material based on size.

Terashima et al., in view of Hildenbrand et al., do not teach the analysis element with asymmetry/symmetry ratios greater than or less than 2. It would have been obvious to one of ordinary skill in the art at the time the invention was made to form the test element with asymmetry/symmetry ratio values greater than, equal to, or less than 2 as optimizing a result effective variable requires only routine skill in the art (see MPEP 2144 II B, and *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980)).

11. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Terashima et al., (US 4,839,278) in view of Tanaka et al., (US 4,990,457).

12. With regards to claim 7, Terashima et al., teach a multilayer analysis element comprising a functional layer, a porous liquid sample spreading layer, and a water impermeable support (abstract, column 3 lines 25-28, column 8 lines 5-18). Terashima et al., do not teach the organic polymer as polyethersulfone, polysulfone, or a mixture thereof. Tanaka et al., recite a microporous analysis element in which the microporous structure can be made from polysulfone (column 5 lines 30 and 31, column 6 lines 33 and 34). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Terashima et al., in view of Tanaka et al., to gain the advantage of analyzing a whole blood sample irrespective of the amount of cells in the sample as taught by Tanaka et al.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dwan A. Gerido, Ph.D. whose telephone number is (571)270-3714. The examiner can normally be reached on Monday - Friday, 9:00 - 6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lyle A Alexander/
Primary Examiner, Art Unit 1797

DAG